Written on SEPTEMBER 13, 2011 AT 10:11 AM *by* PDILLARD

Navy Medical Researchers Move Close to an Effective Malaria Vaccine

Filed under UNCATEGORIZED [NO COMMENTS]

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Everyone is familiar with the idea that when Navy personnel and their families deploy to regions where malaria is endemic, they are at risk of developing infection with this life-threatening disease. In fact, more person-days have been lost among U.S. military personnel due to malaria than to bullets during every military campaign fought in malaria-endemic regions during the 20th century. For the families of the deployed, the threat of malaria can be just as significant.

Although scientists have been working for decades, we still have no licensed vaccine to prevent malaria. It is clear that the DoD needs a vaccine which can be given prior to deployment to completely block infection, similar to the vaccines we provide for other infectious disease threats to our military personnel and their dependents.

To address this threat, researchers from the Naval Medical Research Center, U.S. Military Malaria Vaccine Program (USMMVP), have dedicated themselves to the development of an effective malaria vaccine. On Thursday, Sept 8th, Navy researchers and their collaborators published a research article online in the prestigious journal, Science, describing exciting new results in the development of a vaccine to prevent infection with Plasmodium falciparum, the most dangerous species of malaria parasite.

The approach described in the article in Science goes back to studies which were begun by researchers from the U.S. Navy and the University of Maryland in the early 1970's. Together with investigators from the Walter Reed Army Institute of Research (WRAIR), these scientists went on to develop a robust model of immunity to malaria.

The investigators showed that high levels of protection against malaria infection could be achieved in humans who were immunized by the bite of mosquitoes that inoculated live, sporozoite (early) stage Plasmodium falciparum parasites that had been weakened by irradiation. Immune cells called cytotoxic or killer CD8+ T cells that are activated in humans

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by the sporozoites are responsible for the protection against malaria after immunization with irradiated sporozoites.

In fact, the mosquito-delivered "radiation-attenuated sporozoite model" became a "gold standard" for showing protective immune responses against the parasite. In more recent studies, other researchers have shown that high levels of protection can also be achieved in individuals exposed to multiple rounds of infected mosquitoes followed immediately by drugs. However, it is clear that we cannot use containers of mosquitoes to "vaccinate" people against malaria!

In the manuscript, my colleagues and I describe how the Navy, along with the University of Maryland, served as testing sites for a first-in-humans trial of an injectable vaccine made up of purified radiation-attenuated parasites. The vaccine, the PfSPZ Vaccine, developed and manufactured by the biopharmaceutical company, Sanaria Inc., in Rockville, Md., was administered into the skin of these volunteers, as are conventional vaccines. WRAIR investigators were responsible for conducting the "challenge" of the immunized volunteers against the bites of infected mosquitoes. While the human trial was being conducted, collaborators at the Vaccine Research Center, the National Institute of Allergy and Infectious Disease, and the National Institute of Health conducted studies of the vaccine in the non-human primate model with the vaccine administered by the intravenous route; altering the route greatly enhanced the body's immune responses to the vaccine.

The publication reports on several main scientific points:

1. The PfSPZ vaccine composed of whole, radiation attenuated (weakened) sporozoites has been manufactured in accordance with U.S. Food and Drug Administration standards for clinical testing and has now undergone initial testing in volunteers.

2. The PfSPZ vaccine was shown to be safe in the 80 volunteers who received doses of the vaccine.

3. When the PfSPZ vaccine is administered by needle and syringe injection into the skin of human volunteers, immune responses and protection against infection are sub-optimal.

4. When the PfSPZ vaccine is administered by intravenous injection to non-human primates and other animals, the sporozoites trigger extremely high levels of malaria parasite-specific killer T cells (cytotoxic CD8+ T cells) in the liver that can confer high levels of protection. Such levels in the liver have never been seen before.

With the publication of this research article, we are entering a new phase of malaria vaccine development. The U.S. Navy is proud to be part of this ground-breaking work and we look forward to the work ahead as we develop a safe and effective malaria vaccine for our operational forces. In addition, in the long tradition that the DoD has for transitioning life-saving interventions to those outside the DoD, we believe that such a vaccine could be equally useful to those in the developing world who are threatened by malaria on a daily basis.

Our work continues...

This article originally appeared in DoDLive http://www.dodlive.mil/index.php/2011/09/medical-monday-navy-medical-researchers-move-close-to-an-effective-malaria-vaccine/

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